(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

§ 882.4525 Microsurgical instrument.

(a) *Identification.* A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

§ 882.4535 Nonpowered neurosurgical instrument.

(a) *Identification.* A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

§ 882.4545 Shunt system implantation instrument.

(a) *Identification.* A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

(b) *Classification.* Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§ 882.4560 Stereotaxic instrument.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

(b) *Classification.* Class II (performance standards).

§ 882.4600 Leukotome.

(a) *Identification.* A leukotome is a device used to cut sections out of the brain.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

§ 882.4650 Neurosurgical suture needle.

(a) *Identification.* A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 198965 FR 2319, Jan. 14, 2000]

§ 882.4700 Cottonoid paddie.

(a) *Identification.* A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

(b) *Classification.* Class II (performance standards).

§ 882.4725 Radiofrequency lesion probe.

(a) *Identification.* A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

(b) *Classification.* Class II (performance standards).